Philip Morris International Management S.A.

Comments to the World Health Organization on

Measurement of Tar, Nicotine and Carbon Monoxide

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Introduction

This paper sets out Philip Morris International's comments on the methods used for measuring tar, nicotine and carbon monoxide yields for cigarettes.

The methods for measuring tar, nicotine and carbon monoxide in a number of countries in the world are the ISO methods,[1] which have been in existence for over 30 years. In recent years, the use of these machine-based results as a basis for providing information to consumers has come under considerable and increasing criticism by many in the public health community. Some public health authorities have called for substantial revisions to the methodology and some believe the methods should be abandoned altogether as they potentially mislead consumers.

Philip Morris International shares the public health community's concerns about reporting ISO yields to consumers. The ISO methods play an important role in the regulation of tobacco products, even thought they have limitations when used as a basis for consumer information. Such methods are necessary in countries that wish to impose maximum yield requirements on cigarettes. They are also critically important tools for researchers as they provide a basis for maintaining a historical perspective that allows one product to be compared to another, the study of the relationship between smoking and disease, and the pursuit of means to reduce the harm caused by smoking. ISO machine based methodologies currently represent the most widely accepted and used standardized measurement system for such purposes.

While the ISO methods are both robust and reliable for measuring the tar, nicotine and carbon monoxide yields of cigarettes, the results they generate cannot serve as a useful tool for communicating the consumers.

We strongly believe there should be research into how to improve the current methods, and that there should be regulatory action on how tar and nicotine information is communicated to consumers. We also believe that recognized international organizations like the European Union and the World Health Organization should take the lead in developing and introducing new regulations dealing with consumer communication.

In this paper, we address the history and science underlying the development of the existing ISO methodology and the current understanding of its limitations. We also outline possible regulatory action regarding tar, nicotine and carbon monoxide measurements.

We would be happy to discuss in greater detail any of the issues raised in this paper.

Background: The 1950s to the Late 1990s

The Development of the FTC/ISO Measurement Methods

In the 1950's, evidence began to emerge pointing to a link between cigarette smoking and lung cancer and scientists identified a possible "dose-response relationship," meaning that various scientific studies found that the incidence of tumors increased as the exposure to tar increased.[2]

This finding of a dose-response relationship led some prominent scientists and public health authorities to recommend the development of cigarettes that would reduce the amount of tar inhaled.[3]

In 1966, a committee of experts appointed by the U.S. Public Health Service concluded that "the preponderance of scientific evidence strongly suggests that the lower the tar and nicotine content, the less harmful would be the effect."[4] As a result, the committee recommended to the U.S. Surgeon General "that action be encouraged which will result in the progressive reduction of the 'tar' and nicotine content of cigarette smoke."[5]

In response to these recommendations, in 1966 the U.S. Federal Trade Commission (FTC) decided to permit cigarette manufacturers to advertise the tar and nicotine content of their cigarettes.[6] However, there was no officially recognized method for measuring tar and nicotine levels in cigarettes and a standardized means of measurement was needed. After holding hearings and receiving submissions on possible testing methods, the FTC adopted the Cambridge method in 1967 and began testing all U.S. cigarettes in its own laboratories according to this method.[7]

The Cambridge method is a machine-based system in which a "smoking machine" is used to determine how much tar and nicotine is delivered under standardized smoking conditions. The machine measures tar and nicotine yields by puffing each cigarette at 60

second intervals, with a 35 ml puff volume and a two second puff duration.[8] This testing system became known as the "FTC method."

The FTC's machine-based testing system was quickly adopted as the worldwide standard for measuring tar and nicotine yields. Outside of the United States, most testing has been conducted according to the ISO methods.[9] The ISO methods are virtually identical to the FTC method, using a smoking machine that puffs each cigarette at 60 second intervals, with a 35 ml puff volume and a two second puff duration.[10]

Limitations of the FTC/ISO Measurement Methods

Machines versus Humans

From the beginning, it was recognized that a machine-based testing method could not measure how much tar and nicotine would actually be delivered to any individual by any cigarette. Machines smoke every cigarette in the same way, based on a standard number of puffs, volume of puffs and duration of puffs. However, individuals do not smoke in such a standardized fashion – different people may smoke cigarettes in very different fashions and even individuals may vary their smoking behavior from one cigarette to another.

In hearings before the FTC in 1966, the U.S. tobacco industry, including Philip Morris, commented on the limitations of the FTC method. As the industry explained in its submission:

> "The [Cambridge] Method does not measure the volume of smoke – or the PM [particulate matter] or nicotine in the volume of smoke – that any human being will draw from smoking any particular cigarette. Each smoking characteristic is leveled or averaged out by the standard method."
>
> . . . "No two human smokers smoke in the same way. No individual smoker always smokes in the same fashion"
>
> . . . "The [Cambridge] Method does not and cannot measure these many variations in human smoking habits".[11]

Switchers May Compensate

When the FTC/ISO testing methods were introduced, the public health community was also aware of the possibility that individuals might "compensate" when switching to a cigarette with lower tar and nicotine yields. "Compensation" means that when switching from a stronger cigarette to a lighter one, an individual might take more frequent puffs or longer puffs. It was understood that with compensation, an individual's up-take of tar and nicotine would certainly be greater than the yields reported under the FTC/ISO methods.

Notwithstanding these known limitations of the FTC/ISO methods, governments adopted them to provide a uniform means of measuring tar and nicotine yields.

Scientific Evidence Seemed to Support FTC/ISO Methods

Epidemiological Findings

Shortly after the adoption of the FTC/ISO methods, epidemiologic evidence began to emerge indicating that switching to cigarettes with reduced tar and nicotine yields (as measured by these methods) might reduce the risk of lung cancer.

Beginning in the late 1960s, epidemiologists began to publish studies comparing the disease rates of individuals who smoked lower yield cigarettes as measured by the FTC/ISO methods, and those who smoked cigarettes with higher yields. These studies generally found that those who smoked lower yield cigarettes had a reduced risk of lung cancer as compared to those who smoked higher yields.[12, 13, 14, 15]

In Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine, the U.S. National Cancer Institute (NCI) collected and summarized the numerous epidemiologic studies that have been conducted over the last 35 years examining the impact of yield reductions on lung cancer risk.[16] Monograph 13 concluded: "the clear impression from these studies taken as a whole is that there is a lower risk of lung cancer among populations of smokers who use lower yield products."[17]

The Epidemiological Findings and Compensation

These epidemiologic findings were considered to be particularly significant because they measured risks based on how people actually smoked lower-yield cigarettes, meaning that they inherently took into account any compensation which may occur.[18] This was understood to mean that the epidemiological findings of reduced risk for lower-yield cigarettes were valid even if people who smoked lower-yield products compensated by smoking the cigarettes more intensely.

Although the public health community was concerned about and continued to research the issue of compensation, it generally concluded that compensation was not complete – that is, individuals would take in less tar and nicotine when switching to a cigarette with lower machine-measured yields, although the reduction would not necessarily be as much as would be indicated by the FTC/ISO measurements.[19, 20, 21]

Conclusions of the Public Health Community

Based largely on the epidemiologic evidence described above, from the 1970s through the mid-1990s, the public health community generally concluded that the FTC/ISO measurement methods were valuable despite their known limitations. The general

understanding was that those who switched to lower-yield cigarettes, as measured by these methods, should reduce their risk of lung cancer.

As the WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob) stated in its 2002 report: "for nearly three decades, the ISO/FTC methods were relied upon as meaningful predictors of the differences in exposure to tar, nicotine, and carbon monoxide received by smokers of brands with different machine measured yields."[22]

As a result, public health authorities throughout the world encouraged the development of cigarettes with lower FTC/ISO yields and specifically advised switching to these lower-yield cigarettes. For example:

- In 1971, the Second World Conference on Smoking and Health concluded that individuals should be encouraged "to use low-tar and low-nicotine cigarettes" and that "the manufacturer should be encouraged to produce cigarettes with increasingly lower tar and nicotine yields."[23]

- In 1988, the United Kingdom Department of Health issued a poster recommending that people chose "a brand of cigarette in a lower tar group than the brand you smoke at present."[24]

- In 1989, the American Cancer Society issued a brochure, "Cancer Facts & Figures," that recommended that "those who are not yet able to quit would be well advised to switch to brands with the lowest possible tar and nicotine (T/N) content."[25]

- In 1998, the U.K. Scientific Committee on Tobacco and Health recommended that a "policy of further tar reduction in manufactured cigarettes should be pursued."[26]

Regulatory Response

Regulatory trends, particularly in Europe, closely followed the conclusions of the public health community.

The United Kingdom was one of the first countries in Europe to regulate tar and nicotine yields. In 1971, the Royal College of Physicians, determined that "cutting down the tar delivery of cigarettes might lessen the danger of cancer" and recommended that the tar and nicotine content of all marketed brands of cigarettes should be published.[27] Based on this, the UK Government introduced a program to reduce tar and nicotine yields. This was implemented through a series of voluntary agreements with the industry. In 1980, the agreement was revised to prohibit advertising of cigarettes with a tar yield greater than 20 mg and the introduction of a tar ceiling for any new brands, which was to decrease to 15 mg by 31 December 1983.[28]

In 1979, Spain established a ceiling of 16 mg of tar and 1 mg of nicotine, as measured by ISO methods, for "low tar and nicotine" cigarettes.[29] In 1982, it imposed yield ceilings for new products of 24 mg of tar and 1.8 mg of nicotine.[30]

In 1982, Portugal established a categorization system for cigarette brands based on machine-measured tar and nicotine yields (similar to the system in the U.K.) and required yield ceilings to be established, "which should be progressively reduced."[31] In 1983, yield ceilings were set at 28 mg of tar and 2 mg of nicotine.[32]

In France, the Health Ministry reached an industry agreement in 1987 providing for the reduction of average tar yields to 15 mg by 1990 and 13 mg by 1993.[33]

The European Union became involved in these issues in the mid-to-late 1980s. The EU's efforts were prompted by its "Europe Against Cancer" program, initiated 1985, which established an independent Committee of Cancer Experts to advise on cancer prevention measures. In 1986 the Committee concluded that "it is now an established fact that the lower the tar content of the tobacco smoked, the less the risk of lung cancer to the smoker."[34] The Committee recommended the imposition of an EU ceiling on tar and nicotine yields.[35] As a result, a 1989 Council Directive required the printing of tar and nicotine yields, as measured by ISO methods, on all cigarette packages.[36] One year later the EU adopted a Directive which imposed ceilings on ISO-measured tar yields of 15 mg by December 31, 1992, and 12 mg by December 31, 1997.[37]

The Late 1990s to the Present

Concerns about the Accuracy of the Methods

By the late 1990s, the public health community had become increasingly concerned that the FTC/ISO methods were inaccurate and possibly even misleading. There was particular concern that individuals who switched to cigarettes with lower FTC/ISO yields were not actually taking in less tar and nicotine, and thus were not actually reducing their lung cancer risk.

These concerns were driven largely by data suggesting that the degree of compensation was much greater than had previously been assumed, and that lung cancer rates had not declined for certain populations to the extent that would have been expected if the reductions in tar and nicotine yields were in fact beneficial.

In 2000, the WHO issued a Monograph, Advancing Knowledge on Regulating Tobacco Products, which stated that the FTC/ISO measurements are "seriously flawed" and thus do not present an adequate basis for regulation.[38] The Monograph, incorporated the recommendations of the WHO's 2000 Oslo Conference, which included:

- the removal of "tar and nicotine measures derived from ISO/FTC methods from packages."[39]

- the prohibition of descriptors such as "light" that "have the aim or effect of implying a reduced health risk attributable to low tar or nicotine measurements."[40]

- the discontinuation of "harm reduction strategies based on naïve interpretation of tar and nicotine yield measurements," including "abandoning the strategy of seeking lower nominal tar yields."[41]

- the "development of better measurements of the constituents and impact of tobacco products with the aim of substantially reducing their toxicity."[42]

In 2002, the World Health Organization's Scientific Advisory Committee on Tobacco Product Regulation ("SACTob"), issued conclusions regarding ISO methods to measure cigarette yields and stated: "Tar, nicotine and CO numerical ratings based on current ISO/FTC methods and presented on cigarette packages and in advertising as single numerical values are misleading and should not be displayed." [43]

Monograph 13

The issue was also being considered in the United States and in November 2001, the US National Cancer Institute published Monograph 13 which reviewed evidence to determine whether individuals reduced their lung cancer risk when switching to lower-yield cigarettes as measured by the FTC/ISO method.[44] Monograph 13 concluded:

> "There is no convincing evidence that changes in cigarette design between 1950 and the mid 1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population." [45]

As a result, Monograph 13 concluded that the existing machine-based FTC/ISO measurements do not provide meaningful information for smokers:

> "Measurements of tar and nicotine yields using the FTC method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette. The measurements also do not offer meaningful information on the relative amounts of tar and nicotine exposure likely to be received from smoking different brands of cigarettes." [46]

Monograph 13 sets out the reasons for this change of direction by the public health community regarding the merits of the FTC/ISO methods. The paper focused particularly on two lines of evidence that it believed were inconsistent with a beneficial impact of reductions in FTC/ISO yields on lung cancer risk.

First, Monograph 13 rejected the previous conclusions regarding the amount of compensation when switching from higher-tar to lower-tar products. The paper interpreted published data on compensation to conclude that it was generally "complete." In other words, the Monograph concluded that individuals who switched to lower-yield cigarettes would smoke them in such a way that they would continue to take in the same amount of tar and nicotine that they had with the higher-tar cigarettes. The Monograph stated: "for spontaneous brand switchers, there appears to be complete compensation for nicotine delivery, reflecting more intensive smoking of lower-yield cigarettes."[47] Given this conclusion, the Monograph determined that "there is little reason to expect that smokers of low-yield cigarettes will have a lower risk of disease than those who smoke higher yield cigarettes."[48]

Second, Monograph 13 examined population trends in lung cancer rates in both the United States and the United Kingdom, on the assumption that if the reductions in FTC/ISO yields were beneficial, "they must impact the rates of disease actually occurring in the population of smokers who use these cigarettes."[49] Although the Monograph noted that "lung cancer death rates in both the United States and United Kingdom have declined among males in recent years,"[50] it determined that the reductions in the US death rates could be explained entirely by changes in smoking prevalence, while reductions in UK death rates could be accounted for by factors other than machine-measured tar reduction.

In addition, the Monograph emphasized that there was evidence that "both relative and absolute risks of lung cancer in smokers have risen from the 1950s through the 1980s," during a period of time in which FTC/ISO yields had dropped dramatically, which suggested that yield reductions had not reduced lung cancer risk.[51]

It is important to note that Monograph 13 did not conclude that lower-yield cigarettes, as measured by the FTC/ISO methods, are not safer than higher-yield cigarettes. Rather, the Monograph concluded that at this time, there is no "convincing evidence" that yield reductions had been beneficial.[52] Subsequent scientific studies still indicate that low yield cigarettes may reduce somewhat the risk of lung cancer for the overall population of smokers. For example, in its 2003 World Cancer Report, published after Monograph 13, IARC noted that although low yield smokers compensate, "the risk of lung cancer is slightly lower among smokers of low-tar and low-nicotine cigarettes than among other smokers."[53]

Other Concerns

Recently some public health officials and scientists have also begun to question one of the fundamental premises of the existing measurement method – that "tar" (which is a collection of the substances that are produced when a cigarette is burned, other than nicotine, gases, and water) can be used as a reliable indicator for the amount of harmful constituents inhaled by an individual.

There is emerging evidence indicating that individual constituent yields may not always be directly correlated with FTC/ISO measured tar yields. Some scientists have also argued that the quality of the "tar" of one cigarette is not necessarily the same as the "tar"

of another cigarette, even if the quantity is the same. As a result, recent scientific publications have concluded that the use of "tar" as a "catch-all name for a wide range of chemicals" may be "simplistic and misleading," and that the measurement and disclosure of individual constituents may be preferable.[54]

Reporting on individual constituents would also be of paramount importance for products designed to reduce exposure to certain potentially harmful smoke constituents.

Alternate Testing Methods

Certain governments have already explored the possibility of revising the existing FTC/ISO measurement system. For example:

The Commonwealth of Massachusetts

The Commonwealth of Massachusetts in the United States has played a leading role in exploring alternatives to the FTC/ISO testing regime and in 1998 adopted what has become known as the "Massachusetts method" for measuring tar and nicotine yields.

The Massachusetts method uses the same smoking machines as the FTC/ISO methods but tests the cigarettes under intensified smoking conditions in order to reflect compensation. The smoking parameters for the machines have been altered to a 45 ml puff volume, a 30 second interval between puffs, and the blocking of 50% of the ventilation holes in the cigarette filter.[55] When cigarettes are tested under these conditions, tar and nicotine yield measurements generally increase, although the relative rankings between brands generally remain the same.[56]

Canada

Canada has similarly modified the FTC/ISO testing methods to take individuals' compensation into account. Under the Canadian method, cigarettes are tested under two sets of smoking conditions, one of which is intended to reflect intensified smoking:

1. the standard conditions of the ISO machine-smoking methods, with a 35 ml puff every 60 seconds and with all ventilation holes unblocked; and

2. intensified smoking conditions using the ISO machine-smoking methods, in which the puff volume is increased to 55 ml, the puff interval is decreased to every 30 seconds, and all ventilation holes are completely covered with tape.[57]

In Canada, manufacturers are now required to print two different sets of yield measurements on cigarette packages: those derived by the ISO methods and those derived by the intensified smoking conditions.

According to Physicians for a Smoke-Free Canada, the intensified smoking parameters adopted by Canada "more closely mirror realistic smoking conditions."[58] Although the test still relies on "smoking machines," the "machine smokes more like a real person does."[59] The intensified testing conditions produce much higher tar and nicotine yields; for instance, tar yields for lower-yield cigarettes increase on average by 274% as compared to those measured by ISO.[60]

Limitations of These Alternate Testing Methods

It is important to note that both the Massachusetts and the Canadian methods have the same limitations as the FTC/ISO methods in that no machine measurement can indicate the precise amount of tar and nicotine an individual will inhale from any particular cigarette. [1]Machine-measured yields report the relative differences in yields among different brands when the cigarettes are held and smoked by the machine under standard conditions. These reported yields will not necessarily reflect, however, the amount actually inhaled by any person because people do not smoke like the machines used in the test methods.

The European Union's Approach in 2001

As scientists and public health authorities became increasingly concerned in the late 1990s that the FTC/ISO methods may be misleading and that yield reductions may not be beneficial, the EU responded by adopting Directive 2001/37. The Directive attempts to strike a balance between the existing regulatory regime and the emerging concerns about the ISO methods.

On the one hand, the Directive changes course by prohibiting descriptors, such as "low tar" and "light," that are used by many manufacturers to reflect differing tar and nicotine yields as measured by the ISO methods. The Directive states that such descriptors "may mislead the consumer into the belief that such products are less harmful and give rise to changes in consumption."[61] This prohibition is a significant change from previous regulatory regimes. As noted above, governments such as the U.K. and Portugal had previously required that cigarettes with lower machine-measured yields should be categorized as "low tar," which would now be prohibited under the Directive.

On the other hand, notwithstanding the emerging concerns about the ISO methods, the Directive reaffirms the use of these methods. Although the Directive acknowledges that "subsequent research" should be conducted to "develop and use more precise and reliable measurement methods," it requires that the ISO methods be used as the standardized methodology for all yield measurements.[62] The Directive also continues the policy of imposing yield ceilings based on ISO measurements.[63]

While the Directive prohibits the use of descriptors to reflect yield measurements, it requires manufacturers to inform consumers about the specific tar and nicotine yields based on ISO measurements, by printing the yield numbers on the side of the pack [64] and by requiring Member States to ensure that a list of tar and nicotine yields "is made public."[65]

Developing New Testing Methods

Various new methods for testing tar and nicotine yields have been explored in recent years in order to find a system which is more consistent with human smoking behavior.

Actual nicotine deliveries have been measured by using human biomarkers which allow researchers to determine an individual's exposure by measuring levels of certain tobacco smoke chemicals or metabolites in human blood, saliva, urine, or exhaled air. For example, a 2001 large-population study in the UK determined nicotine deliveries by measuring continine in saliva.[66] Some other human biomarkers of exposure exist which allow measurement of other smoke constituents, such as carbon monoxide.

It has been suggested that such data, which can be obtained through clinical studies, could be used to model smoking machine parameters in order to more accurately predict actual human intake of various constituents of different brands of cigarettes. Various models have been proposed,[67] but it may be some years before sufficient human data has been collected and analyzed and the proposed models have been validated. However, it does appear that future investigation is primarily focused on actual human exposure rather than relying solely on machine measurements.

Philip Morris International is in the early stages of research that could provide valuable data for developing new methods. For example, we are analyzing data obtained from clinical studies in which individuals switch from their normal cigarette to cigarettes of lower machine-reported tar delivery. These data are collected under completely controlled conditions, so no one may smoke any cigarettes other than those specifically designated. Actual nicotine uptake for these individuals is determined by measuring nicotine plus five metabolites of nicotine.

Our preliminary research suggests that once there is sufficient data, smoking machine parameters (primarily puff volume and puff frequency) can be modeled to obtain tar and nicotine yields for these cigarettes that reflect the actual average uptake. A very large ongoing study by our affiliated company, Philip Morris USA, involving 4,000 people will provide additional data for analysis.

It is hoped that this research will assist in establishing more accurate methods for measuring tar and nicotine yields, and we would be happy to provide you with further details.

Current Regulatory Initiatives

Philip Morris International recognizes that the measurement of tar and nicotine yields and communicating about these yields to consumers is a complex and evolving issue. We

share the concerns of the public health community regarding the limitations of the existing FTC/ISO methods and we are anxious to work with regulators and the public health community to develop alternative methods of measurement and communication to consumers regarding the relative yields of cigarette products.

We strongly believe research should be conducted to improve current methods and there should be regulatory action on how this information is communicated to consumers. International organizations like the European Union, the World Health Organization and ISO should take the lead in assessing whether better measurement methods can be developed and should participate in developing and implementing any new standards. EU Directive 2001/37/EC identifies testing methods as a matter for the EU Commission to investigate.

It will take time to develop and validate any new methods. In the meantime, we believe governments should consider whether and how to report ISO testing yields to consumers.

If governments do not currently require ISO numbers to be communicated to consumers, we believe it should not now introduce such a requirement.

If governments currently do require ISO numbers to be communicated to consumers, they may determine that this is no longer appropriate, even though manufacturers may still be required to measure yields according to ISO methods and report these to the government. Manufacturers may also be required to respect maximum yields, based on ISO measurements. Philip Morris International believes this is an appropriate regulatory step given the limitations of the ISO methods.

If governments decide that ISO numbers should continue to be reported to consumers, we believe governments should also require that consumers be advised of the limitations of these machine-generated numbers. This could be accomplished by requiring information to be placed next to the tar and nicotine yields, which informs consumers about the limitations of the ISO measurement methods. The information communicated could state, for example, that low-yield cigarettes have not been proven to be less hazardous than other cigarettes and are not a substitute for quitting; that the amount of tar and nicotine that an individual obtains from a cigarette depends on how the individual smokes the cigarette; that individuals may intake more tar and nicotine than measured by the ISO testing methodology; and that lower tar cigarettes do not make it easier to quit smoking. It is also important to inform consumers that this information does not in any way suggest that they should choose to smoke cigarettes with higher yields than they currently choose to smoke; the important information for consumers is that there is no safe cigarette and that the best thing to do it to quit.

Conclusion

Philip Morris International has developed and is implementing an expanded program of communications to consumers about cigarettes and the health risks of smoking, including

information about tar and nicotine numbers and what they mean. This program is being rolled-out around the world and includes a range of communication vehicles, including placing leaflets on cigarette packs, point-of-sale materials, brochures and paid announcements, as permitted by local laws.

Philip Morris International would be pleased to discuss the issues raised in this paper and any regulatory solutions the government considers appropriate. As indicated, we believe any regulatory solutions should also reflect the need to develop better testing methods based on research of actual human smoking behavior.

[1] Methods developed by the International Organization for Standardization. The current methods, as referenced in Directive 2001/37/EC, are: 4387 for tar, 10315 for nicotine and 8454 for carbon monoxide.

[2] For instance, laboratory researchers who painted condensate from tobacco tar on the skin of mice found that they could significantly reduce the likelihood of skin tumors developing by decreasing the applications of tar. *See, e.g.*, E.L. Wynder, et al., "A Study of Tobacco Carcinogenesis. II. Dose-Response Studies." *Cancer* 10(6): 1193-1200 (1957).

[3] For example, in 1957, one of the pioneers of smoking and health research, Dr. Ernst Wynder, recommended reductions in tar as a possible means of reducing lung cancer risk: *"It may be predicted that if the average smoker were exposed to only one half the amount of tobacco tar to which the smoker of regular-sized cigarettes is now exposed, his cancer risk would be significantly reduced."* E.L. Wynder, et al., "A Study of Tobacco Carcinogenesis. II. Dose-Response Studies." *Cancer* 10(6): 1193-1200, at 1199 (1957).

[4] United States Senate, Consumer Subcommittee of the Committee on Commerce, *Reviewing Progress Made Toward the Development and Marketing of a Less Hazardous Cigarette*, 90th Congress, 1st Session. 7-8, at 7. Washington: GPO, 1967 (emphases added). The committee's written report was circulated in 1966, but was not formally submitted to Congress until 1967.

[5] United States Senate, Consumer Subcommittee of the Committee on Commerce, *Reviewing Progress Made Toward the Development and Marketing of a Less Hazardous Cigarette*, 90th Congress, 1st Session. 7-8, at 7. Washington: GPO, 1967 (emphases added).

[6] *See* Trade Regulation Reporter ¶ 39,012, at 41,603 (CCH 1995).

[7] Press Release, Federal Trade Commission, FTC to Begin Cigarette Testing (August 1, 1967); Testing for Tar and Nicotine Content, 32 Fed. Reg. 11178 (Aug. 1, 1967).

[8] Testing for Tar and Nicotine Content, 32 Fed. Reg. 11178 (Aug. 1, 1967).

[9] Scientific Advisory Committee on Tobacco Product Regulation, "Recommendation on Health Claims Derived from ISO/FTC Method to Measure Cigarette Yield' (WHO/NMH/TFI/02.02); *see also* WHO Monograph, *Advancing Knowledge on Regulating Tobacco Products* at 16 (2000).

[10] *See, e.g.*, ISO 3308, "Routine Analytical Cigarette-Smoking Machine – Definitions and Standard Conditions" (3d ed. 1991); WHO Monograph, *Advancing Knowledge on Regulating Tobacco Products* at 16 (2000).

[11] Supplemental Observations Following November 30, 1966 Hearing Before the Federal Trade Commission at 2-3 (emphases in original).

[12] For example, in 1976, the American Cancer Society published an epidemiological analysis of its Cancer Prevention Study ("CPS-I"), a groundbreaking study that tracked over one million Americans for a 12-year period. The study categorized its subjects as either "high," "medium," or "low" yield smokers, as determined by machine-measured yields. The study found that, compared to smokers of high yield cigarettes, subjects who smoked low yield cigarettes were 26% less likely to die from lung cancer, and even smokers of medium yield cigarettes reduced their risk by 10%. E.C. Hammond, et al., "'Tar' and Nicotine Content of Cigarette Smoke in Relation to Death Rates," *Environmental Research* 12: 263-274 (1976).

[13] In 1986, the American Cancer Society published the results of its CPS-II study (the follow-up to the CPS-I study), in which it found that "doubling the tar yield would be equivalent to an increased risk of about 40%." L. Garfinkel & S. Stellman, "Smoking and Lung Cancer in Women: Findings in a Prospective Study," *Cancer Research* 48: 6951-55 (1988).

[14] In 1992, an epidemiological study conducted by Dr. Wynder projected a 15-20% reduction in lung cancer risk for every 10 mg reduction (as measured by the FTC/ISO method) in tar yields. E.A. Zang & E.L. Wynder, "Cumulative Tar Exposure: A New Index for Estimating Lung Cancer Risk Among Cigarette Smokers," *Cancer* 70(1): 69-75 (1992).

[15] In 1995, the *British Medical Journal* published a combined analysis of four British epidemiological studies, in which the researchers found that: "about a quarter of deaths from lung cancer, coronary heart disease, and possibly other smoking related diseases could be avoided by switching from higher tar cigarettes (30mg/cigarette) to lower tar ones (15mg/cigarette)." J.L. Tang, et al., "Mortality in Relation to Tar Yield of Cigarettes: a Prospective Study of Four Cohorts," *British Medical Journal* 311: 1530-1533, 1533 (1995).

[16] A list of these studies can be found at Table 4-1 in Monograph 13.

[17] NCI Monograph 13 at 81.

[18] For example, Dr. Jonathan Samet – Chairman of the Department of Epidemiology at Johns Hopkins University – explained in a paper written at the request of NCI: "Epidemiologic research has had a central role in characterizing the consequences of the changing cigarette because it supplies direct information on the consequences of varying tar and nicotine yield products. Thus, the findings inherently consider compensatory changes in inhalation patterns or in numbers of cigarettes smoked and provide the evidence needed to answer the question of immediate public health relevance: whether disease risk varies with cigarette tar and nicotine yield as determined by the FTC method." J.M. Samet, "The Changing Cigarette and Disease Risk: Current Status of the Evidence," in The FTC Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes: Report of the NCI Expert Committee 7: 77-92, 79-80 (1996).

[19] For instance, in 1986, the International Agency for Research on Cancer (IARC) acknowledged that "smokers of 'low tar'-level cigarettes tend to compensate," but concluded that smokers "do not in general compensate fully for lower tar yields." IARC Working Group, *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco Smoking* 38: 312-13 (1986).

[20] Two years later, in 1988, researchers for the American Cancer Society agreed that smokers of lower yield cigarettes "do[] not fully compensate for the total tar inhaled." L. Garfinkel & S. Stellman, "Smoking and Lung Cancer in Women: Findings in a Prospective Study," *Cancer Research* 48: 6951-55 (1988).

[21] As recently as 1994, Dr. Neal Benowitz – recognized as one of the foremost authorities on smoking behavior – argued that compensation, when it occurs, is primarily a temporary phenomenon: *"Overcompensation (i.e., inhaling more smoke from low-nicotine cigarettes than from higher-yield brands) appears, however, to persist only for days or weeks. In long-term studies of carbon monoxide exposure after subjects switched to low-yield cigarettes, compensatory oversmoking appears not to persist".* N. Benowitz & J. Henningfield, "Establishing a Nicotine Threshold for Addiction," *N. Eng. J. Med.* 331;123-25, 125 (1994).

[22] Scientific Advisory Committee on Tobacco Product Regulation, "Recommendation on Health Claims Derived from ISO/FTC Method to Measure Cigarette Yield" (WHO/NMH/TFI/02.02).

[23] "Recommendations," in *Less Harmful Ways of Smoking, A Workshop of the Second World Conference on Smoking and Health, Held in London, England, 20-24 September 1971* (E.L. Wynder, ed., 1972) at 1891.

[24] Health Departments of the United Kingdom, "Tar, Carbon Monoxide and Nicotine Yields of Cigarettes" (January 1988).

[25] American Cancer Society, "Cancer Facts & Figures – 1989," at 21 (1989).

[26] Department of Health, et al., "Report of the Scientific Committee on Tobacco and Health, Chairman: Professor David Poswillo," at 7.21 (1998).

[27] Royal College of Physicians, *Smoking and Health Now* at 132, 138 (1971)

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[41] WHO Monograph, *Advancing Knowledge on Regulating Tobacco Products* at 26 (2000).

[42] WHO Monograph, *Advancing Knowledge on Regulating Tobacco Products* at 34 (2000).

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[45] Monograph 13 at 146.

[46] Monograph 13 at 10.

[47] Monograph 13 at 10.

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[61] Directive 2001/37/EC ¶ 27.

[62] Directive 2001/37/EC ¶ 27; *see also* Directive 2001/37/EC Article 4.1.

[63] Directive 2001/37/EC Article 3.1.

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